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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,100	07/31/2003	Dale L. Partin	DP-309294	7754

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EXAMINER

SUNDARARAMAN, VIKRAM P

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/631,100	Applicant(s) PARTIN ET AL.	
	Examiner Vikram P. Sundararaman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims **1-3, 8, 10, 14-15, 17, 22-24, 31-33** are rejected under 35 U.S.C. 102(e) as being anticipated by Sullivan et al., US 6,984,207 B1, hereinafter referred to as Sullivan.

3. As to **Claims 1 and 23**, Sullivan teaches a “passive physiological monitoring system” [Title] wherein:

- a. a “PVDF film... incorporated into a fluid-filled vinyl pad,” that “is placed on/under/above various locations of the patient.” [Column 7, Lines, 3-5] (locating a fluid-filled bladder in a supportive load-bearing relationship with respect to the subject);

- b. “The piezoelectric element, 1, is a pressure-sensing detector acting as a highly sensitive strain gage providing high dynamic range and linearity.” [Column 7, Lines 10-12] (measuring a fluid pressure in the bladder);

- c. the invention provides a, "device that can be used... to provide an accurate measurement of heart rate, respiration, and blood pressure" [Column 5, Lines 49-54] and "The system provides a tool whereby parameters other than blood pressure, heart rate, and respiration can be measured. These parameters include, but are not limited to, patient movement and sleep habits, pulse strength over various portions of the body, relative blood flow volumes, and cardiac output, among others." [Column 5, Lines 18-23] (isolating a perturbation of the measured pressure due to said periodic physiological process; using variation to detect choking, convulsions, seizures, coughing, maternal contractions or frequency of movement of said subject);
 - d. "Spectral techniques help to identify the frequencies... of the events of interest," [Columns 7-8, Lines 67-02] (identifying and monitoring at least a frequency or period of said perturbation)
4. As to **Claims 2-3**, Sullivan teaches, "cardiac action analysis uses a bandpass frequency limit of 0.1-4.0Hz," [Column 8, Lines 3-4] (wherein the quasi-periodic physiological function is a heart rate of said subject, and the step of isolating a perturbation of the measured pressure includes band-pass filtering perturbations of the measured pressure in the range of about 0.6Hz to 10Hz; wherein the band-pass filtering is in the range of about 2Hz to 7Hz; determining a variability of the isolated perturbation to determine heart rate variability)
5. As to **Claim 8**, Sullivan teaches, "an object of the present invention to provide an accurate measurement of heart rate, respiration, and blood pressure," [Column 5, Lines

52-54] and "Respiration analysis uses a frequency from 0.01Hz-3.0Hz." [Column 8, Lines 4-5] (Wherein the quasi-periodic physiological function is a respiration rate of said subject, and the step of isolating a perturbation of the measured pressure due to said respiration rate includes band-pass filtering perturbations of the measured pressure in the range of about 0.15Hz to 0.5Hz)

6. As to **Claim 10**, Sullivan teaches, "Spectral techniques help to identify the frequencies and amplitudes of the events of interest," [Column 7, Lines 67+] and "a device that can be used... to provide an accurate measurement of heart rate, respiration, and blood pressure" [Column 5, Lines 49-54]. Since respiration rate is monitored, it is understood that the amplitude of perturbations of the respiration signal as measured over time can be used, therefore, as an indication of respiration volume.

7. As to **Claims 11 and 16** it is understood that the variability of the determined amplitude is measured with respect to time

8. **Claim 12**, Sullivan teaches that, "Spectral techniques help to identify the frequencies and amplitudes of the events of interest," [Column 7, Lines 67+] (an indication of subject health, alertness, awareness, or impairment)

9. As to **Claims 14, 32, and 33**, Sullivan teaches, "plural sensors are required for measurements in different locations" [Column 10, Lines 22-23] and also that, "Fig. 8 shows the measurement results of the pulse at two locations along the arm" and further that "this value can be used to correlate systolic and diastolic pressure."

10. As to **Claims 15 and 24**, Sullivan teaches, "The P2M sensor measures all physical impulses in the measuring environment, including the patient's physiological

signals, nearby human noise and activity signals, noise and vibration from the machinery, and electromagnetic (EM) noise emitted from the lights and instrumentation. While the output signal includes all of these signals, many are too weak to affect the measurement while others such as EM noise corrupt the reading. Running the signal through filters and other signal-processing algorithms removes the noise. The conditioned signal is then analyzed through routines, including a fast Fourier transform (FFT) which identifies the primary signal frequencies.” [Column 8, Lines 54-65] Sullivan also teaches that well known in the art “several techniques reduce noise and vibration interferences. Active cancellation uses two piezoelectric sensors, one of which is not in contact with the body. The sensor not attached to the body is exposed to environmentally acoustic and vibrational signals, while the sensor attached to the body is exposed to environmental as well as body signals. Subtraction of one output from the other output yields the body signal of interest.” [Column 7, Lines 52-59] (Independently measuring environmental disturbances that affect the measured pressure and compensating the measured pressure for such independently environmental disturbances)

11. As to **Claim 17** Sullivan teaches that, “Spectral techniques help to identify the frequencies and amplitudes of the events of interest,” [Column 7, Lines 67+] and further teaches that, “In a preferred method of blood pressure measurement passive measurement of blood pressure (systolic and diastolic) may be conducted...” [Column 10, Lines 16-20] (Using said amplitude as an indication of the subject’s health)

12. As to **Claims 22 and 31**, Sullivan teaches, "The passive and autonomous operation of such a system is suitable to telemetry and real-time remote monitoring, and the final feature of the invention is a telemetry design of distance and remote monitoring." [Column 11, Lines 56-60] (automatically communication said medical condition)

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claims 4, 9 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Bakken et al., US 2004/0260348 A1, hereinafter referred to as "Bakken."

15. As to **Claim 4 and 25**, Sullivan teaches the limitations of the claimed invention as described previously in this action. What Sullivan does not teach, however, is determining a variability of the isolated perturbation to determine heart rate variability. Bakken teaches, "measuring intervals between the sensed cardiac signals, a storage device storing the measured intervals, and a microprocessor determining heart rate variability in response to the stored intervals." [Page 1, Paragraph 007] Since both Bakken and Sullivan teach monitoring of heart rate signals, and since it is well known in the art to calculate heart rate variability from monitored heart rate signals, it would have

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been obvious for one with ordinary skill in the art at the time of the invention to modify Sullivan to include determination of a variability of the isolated perturbation to determine of heart rate variability.

16. As to **Claim 9**, it is understood that since Sullivan teaches monitoring of both heart rate and respiration rate that it would have been obvious to determine a respiration rate variability in a similar manner as Sullivan in view of Bakken as described above.

17. **Claims 5-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Gallant et al., US 2003/0149369 A1, hereinafter referred to as "Gallant."

18. As to **Claim 5**, Sullivan teaches the limitation of the claimed invention as previously described in this action. Sullivan further teaches, "Spectral techniques help to identify the frequencies and amplitudes of the events of interest," [Column 7, Lines 67+] and further teaches that, "In a preferred method of blood pressure measurement passive measurement of blood pressure (systolic and diastolic) may be conducted..." [Column 10, Lines 16-20] What Sullivan does not teach however is determining an amplitude of a said perturbation as an indication of differential blood pressure. It is well known that pulse pressure is defined as a difference between systolic and diastolic pressures measurements. To this extent, Gallant teaches, "the pressure waveform obtained from the transducer 422 is analyzed on an interval (e.g., per-beat) basis per step 532 so as to determine the value of pulse pressure for that interval." [Paragraph 0086] Since both Gallant and Sullivan teach using pressure waveforms in the

monitoring and analysis of heart signals, it have been obvious with one with ordinary skill in the art at the time of the invention to modify Sullivan with the teachings of Gallant to determine an amplitude of a perturbation as described as an indication of differential blood pressures from the obtained systolic and diastolic blood pressure values.

19. As to **Claim 6** it is understood that the variability of the determined amplitude is measured with respect to time.

20. As to **Claim 7**, Sullivan teaches that, "Spectral techniques help to identify the frequencies and amplitudes of the events of interest," [Column 7, Lines 67+] (an indication of subject health, alertness, awareness, or impairment)

21. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Jansen, US 6,719,708 B1, hereinafter referred to as "Jansen." Sullivan teaches the aspects of the claimed invention as described above. What Sullivan does not teach is adjusting an inflation level of said bladder to optimize the measured pressure and comfort of the patient. Jansen teaches a "device and method for measuring values from a person lying down, and pressure sensor" [Title] and that "it is also possible for the hardness of the sensor cushions, 11, filled with air or liquid to be varied as a function of control commands from the control unit, 18, in order to relieve the pressure on the person." Both Sullivan and Jansen teach a device and method to measure physiological parameters using a fluid-filled bladder and pressure sensors, and since they both solve a similar problem. Therefore, it would have been obvious for one with ordinary skill in the art at the time of the invention to modify Sullivan with the teachings of Jansen to include this feature.

22. **Claims 20 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Price et al., US 2004/0194220 A1, hereinafter referred to as "Price." Sullivan teaches the aspects of the claimed invention as described above. What Sullivan does not teach is confirming the presence of the subject by determining a weight of the subject from a DC pressure in said bladder. Price teaches a "force optimization surface apparatus and method" [Title] and that "Controller, 18, can further be configured to detect a bed exit by patient 16 based on information from weight sensors, 24, and provide an alert to caregivers accordingly." [Paragraph 0059] Both Sullivan and price teach the use of a bladder surface with pressure sensors to capture physiological signals and that they solve a similar problem. It would have been obvious therefore to modify the invention of Sullivan with the teachings of Price to include a method to confirm the presence of a subject by determining a weight of the subject.

Claim Rejections - 35 USC § 112

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. **Claims 21 and 30** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not obvious to one with ordinary skill in the art to determine, by use of the

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claimed invention, whether a vehicle has overturned or if a subject is still wearing a seatbelt.

25. **Claim 18 and 27** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not describe how it is possible to, for example, nervousness from possible criminal intent, as a function of measure parameters using the disclosed invention.

26. **Claim 19 and 28** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While it may be possible to monitor signals using the disclosed invention, applicant does not disclose how it is possible to determine the incidence of a vehicular collision and/or the presence of a subject in a vehicle after a collision.

27. **Claim 26** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not disclose the determinants of “good health” from a measure of “not moving enough” in communicating to the subject or another.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- e. Sielaff, US 3,727,606;
- f. Scanlon, US 5,515,865; US 5,684,460;
- g. Hubbard, US 2003/0136201 A1;
- h. Toms, US 6,036, 660;
- i. Snyder et al., US 4,686, 999; and
- j. Gerdt et al., US 6,687,424 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 730am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VPS



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